K031277

510K) Summary of Safety and Effectiveness

Date Prepared: April 21, 2003

Submitted by: Jomed Inc.
2870 Kilgore Rd.
Rancho Cordova, CA 95670

Contact Person: Terry Schultz
Regulatory Affairs Manager

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Device Trade Name: JoWire Asahi PTCA Guide Wire

Device Classification Name and Class: Catheter Guide Wire, Class II (21 CFR 870.1330)

Predicate Devices: JoWire Asahi PTCA Guide Wire (K022762)

Device Description:

The JoWire Asahi PTCA Guide Wires are steerable guide wires with a maximum diameter of 0.014" and available in a 300 cm length. The extension wire is connected to the end of the guide wire outside the body. The wire is constructed from stainless steel core wire with varying core lengths and diameters for each design. The core wire and core are soldered. The distal end of the guide wire has a radiopaque tip that is available straight and is made soft to easily bend with the vessel curve. The coating (hydrophilic or silicone) is applied to the distal portion of the wire guide wire. The proximal section of the guide wire is coated with PTFE.

Intended Use:

The JoWire Asahi PTCA Guide Wires are intended to facilitate the placement of balloon dilatation catheters during percutaneous transluminal coronary angioplasty (PTCA) and percutaneous transluminal angioplasty (PTA). The JoWire Asahi PTCA Guide Wires are not to be in the cerebral blood vessel.

Device Technological Characteristics and Comparison to Predicate Device:

The JoWire Asahi PTCA Guide Wires are made of the same materials, available in the same diameters, have a similar design, and have the same indications for use as the predicate devices and other currently marketed PTCA Guide Wires.

510(k) Summary (cont'd)

Performance Data:

Bench and biocompatibility testing were conducted according to the recommendations from relevant guidances to demonstrate that the JoWire Asahi PTCA Guide Wires met the acceptance criteria and performed similarly to the predicate devices. No new safety or effectiveness issues were raised during the testing.

Conclusion:

The JoWire Asahi PTCA Guide Wires are substantially equivalent to the claimed predicate devices and other currently marketed PTCA Guide Wires.

K031277
Premarket Notification [510(k)] Number

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 14 2003

Ms. Terry Schultz
Regulatory Affairs Manager
JOMED, Inc.
15330 Avenue of Science, Suite 200
San Diego CA 92128

Re: K031277
Trade Name: JoWire Asahi PTCA Guide Wires
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX
Dated: April 21, 2003
Received: April 22, 2003

Dear Ms. Schultz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

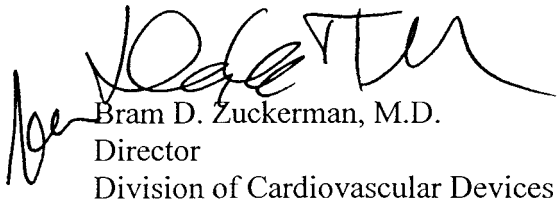
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K031277

Device Name: JoWire Asahi PTCA Guide Wires

Indications for Use:

To facilitate the placement of balloon dilatation catheters during percutaneous transluminal coronary angioplasty (PTCA) and percutaneous transluminal angioplasty (PTA). The JoWire Neo's Guide Wires are not to be used in the cerebral blood vessel.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X (Per 21 CFR 801.19)

OR

Over-the Counter Use _____

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K031277